FILED VIA EFS

WDN:nms 03/27/12 2091647.doc E-021-91

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Pellet and Sanchez-Martinez

Patent No. 6,126,944 Issued: October 3, 2000 Confirmation No. 9684

For: BACULOVIRUS EXPRESSION VECTORS AND RECOMBINANT ANTIGENS FOR

DETECTING TYPE-SPECIFIC ANTIBODIES TO HERPES SIMPLEX VIRUS

Examiner: Kenya A. McLaughlin

Art Unit: 1623

Attornev Reference No. 6395-87124-02

FILED VIA ELECTRONIC FILING SYSTEM

COMMISSIONER FOR PATENTS

PETITION FOR RECONSIDERATION UNDER 37 CFR 1.378(b)

This responds to an Opinion dated January 27, 2012 ("the Opinion") from the Patent and Trademark Office (PTO), dismissing the Petition by the Government of the United States of America ("the Government") to accept late payment of the maintenance fee that was due no later than October 3, 2008 for U.S. Patent No. 6,126,944 ("the '944 patent"). The Petition under 37 CFR 1.378(b) was initially filed May 27, 2011, approximately 2.66 years after the patent expired for non-payment of the 7.5 year maintenance fee. The '944 patent is assigned to the Government and administered by the Centers for Disease Control and Prevention (CDC) where the invention was developed. The Opinion noted that the Government was responsible for possessing knowledge of the need to pay maintenance fees and the due dates for such fees; for instituting a reliable docketing system to provide reminders when maintenance fees became due; and for taking steps to assure that information was correctly entered into the docketing system. The argument that the Government relied on its outside law firms to remind it when the fees were due was said to be insufficient to meet this standard. The Government requests reconsideration of the dismissal of its Petition in view of the additional information submitted herewith.

Page 1 of 7

WDN:nms 03/27/12 2091647.doc E-021-91

The Opinion requested that the Government identify:

- (A) any clerical error was the cause of the approximately 2.66 year delay;
- (B) the business routine that was in place for performing the clerical function that could reasonably be relied upon to avoid errors in its performance;
- (C) that any employee who made the clerical error was sufficiently trained and experienced with regard to the function and routine for its performance that reliance upon the employee represented the exercise of due care by the Government.

The evidence of record illustrates that the April 3, 2008 due date for payment of the maintenance fee for the '944 patent was present in the CDC's Inteum C/S® Intellectual Property (IP) management system ("Inteum database") that has been used by the CDC since at least as early as 2004. The Inteum database is a commercially available IP management database that is widely used by technology transfer offices in the United States. Patent maintenance fee due dates were generated by the Inteum program when the issue date of a patent was entered into the database. For the '944 patent, the issue date was entered at the time of patent issuance on October 3, 2000, and the payment of the 3.5 year maintenance fee was docketed, timely paid, and the entry completed in the database at that time. However, the 7.5 year maintenance fee payment date of April 3, 2008 occurred 12 days before Mr. Valentin Fikovsky began working as a Patent Advisor at the CDC Technology Transfer Office (TTO). After assuming his responsibilities at CDC, Mr. Fikovsky inherited a large patent portfolio containing hundreds of cases each of which had multiple deadlines. The error leading to the expiration of this patent occurred in the context of the transfer of hundreds of files from the Government's prior patent counsel (Needle & Rosenberg) to new patent counsel, and during a time of personnel transition at CDC TTO when the CDC TTO Patent Advisor Russ Metler left CDC in June 2007. Responsibility for the patent portfolio that Mr. Metler managed, which included the '944 patent, was transferred to Suzanne Shope, a Technology Licensing and Marketing Scientist. In addition to her full-time Licensing and Marketing responsibilities, she was the contact person for that portfolio until April 15, 2008 when Mr. Fikovsky began his job as a CDC TTO Patent Advisor.

Contemporaneous with these simultaneous transitions of files and Patent Advisors, the past due date for the initial payment of the maintenance fee was mistakenly overlooked which caused timely payment of the maintenance fee to be missed. Although the maintenance fee date continued to appear on this case in the Inteum database as an uncompleted item assigned to Mr. WDN:nms 03/27/12 2091647.doc E-021-91

Fikovsky, he did not take steps to have the fee paid through one of the outside law firms contracted to pay the fees on behalf of CDC. Mr. Fikovsky has submitted a prior Declaration dated May 27, 2011 (paragraph 7) indicating that during this time he investigated directly paying this fee using a credit card or a maintenance fee payment agency. During that process he overlooked the October 3, 2008 final deadline for paying the maintenance fee. This error led to the non-payment of the fee by the October 3, 2008 deadline.

The Government Reasonably Relied on Mr. Fikovsky's Extensive Prior Experience

A copy of a Curriculum Vitae (CV) provided by Mr. Fikovsky to the Government is attached to the Declaration of Mr. Fikovsky to provide further evidence of the reasons for the Government's reasonable reliance on Mr. Fikovsky's expertise to earry out his duties, timely pay maintenance fees, and take steps to timely revive any patents that expired contrary to the business and public health mission of the CDC.

In October 2008 when the maintenance fee was not paid, Mr. Fikovsky had only recently begun to work at the CDC TTO. However, as noted in his resume, he had been registered as a patent agent since 1982, and he had previously held positions of responsibility such as Director of Patent Prosecution, Biomedical Licensing and Contract Administration from 1983 to 2004 at the University of California. In that position he was a Manager of Patent Prosecution Systemwide, and he was responsible for setting up a system for payment of maintenance fees through CPA. Mr. Fikovsky also supervised a Patent Prosecution Manager who worked with individual case managers in providing timely authorization of maintenance fees that were contained in spread sheets provided by CPA. From 2004 to 2008, Mr. Fikovsky had been the Director of Licensing at the University of Nevada at Reno/Desert Research Institute where he gained additional expertise in the administration of patent portfolios. Mr. Fikovsky was also a member of the Association of University Technology Managers (AUTM) since 1983. The CDC was aware of Mr. Fikovsky's expertise at the time Mr. Fikovsky began to work at CDC, and the Government placed reasonable reliance on him to perform his duties in view of the extensive high level of experience he brought to the job.

Page 3 of 7

WDN nms 03/27/12 2091647 doc E-021-91

When Mr. Fikovsky assumed his role as a Patent Advisor at the CDC on April 15, 2008, he was offered training in docketing and management of his portfolio by Suzanne Shope, who was acting as the interim Patent Advisor for his portfolio. Mr. Fikovsky told Ms. Shope that in view of his extensive experience in the management of patent portfolios, and his expertise as a registered patent agent, additional training was unnecessary. In view of his long career in patent prosecution management (including his assertion that he set up a system at the University of California to pay maintenance fees through CPA), the Government reasonably relied on this experience and expertise in these matters and gave him responsibility for managing his docket. Mr. Fikovsky was aware of the '944 patent and its maintenance fee, as evidenced by an email he sent to Suzanne Shope on May 15, 2008 about the patent and the payment of its maintenance fee. However, as a result of an error and contrary to the desire of the Government, he did not arrange for the timely payment of the 7.5 year maintenance fee that was due for the '944 patent by the patent expiration date of October 3, 2008.

Notice of Expiration Was Not Entered in Inteum Database

The PTO issued a Notice of Expiration for the '944 patent on November 3, 2008 and mailed it to Needle & Rosenberg, the Government's former counsel of record. Needle & Rosenberg forwarded the Notice of Expiration ("Notice") to the Government, and the Notice was received by the CDC TTO on November 28, 2008, which was the day after Thanksgiving. The TTO was short-staffed that day and the Inteum database Program Analyst, Ms. Veronica Brown, was not at the office when the Notice of Expiration arrived. In Ms. Brown's absence, Ms. Sharon Shropshire received the letter and gave it to Mr. Francisco Candal. The Notice was subsequently emailed to Ms. Brown on December 9, 2008 by Ms. Sherwood, but as a result of a docketing oversight by Ms. Brown the Notice was not docketed. If the Notice had been docketed, it would have indicated that the patent had expired and that expiration information would have prompted TTO personnel to seek revival of the patent. For example, the Inteum database entry for the '944 patent was accessed by Donald Prather of CDC TTO at the time he prepared a license agreement for this patent on or about September 3, 2009. At that time Mr. Prather consulted the Inteum database about the '944 patent, and the database indicated the patent was in good standing. Had the Notice of Expiration been docketed the expired status of the patent would have been noted at that time this license was granted and the appropriate steps

WDN:nms 03/27/12 2091647.doc E-021-91

taken to revive it then. However, in the absence of this database information and in view of the hundreds of active matters being prosecuted and maintained by CDC TTO, the petition to revive the '944 patent was not filed until after the status of the patent was checked on PAIR on April 13, 2011 when the Government was calculating the term of the patent.

Experience and Training of Ms. Veronica Brown

Veronica Brown was employed as a secretary at CDC beginning in 1984. In the year 2000 she began working in the CDC TTO as a Technology Transfer Assistant and performed her secretarial duties reliably and well. In view of her performance in that position she was promoted in 2004 to the Management and Program Analyst position that she currently holds. That job requires her to analyze legal documents from intellectual property law firms, extract information from them, and incorporate pertinent data into the CDC intellectual property database. Beginning on approximately October 1, 2007 she became responsible for updating the Inteum IP database by entering patent deadlines into the database. She was trained in the performance of that duty by Cynthia Sherwood, who had worked at CDC TTO as the Inteum database manager since 2002.

Ms. Sherwood reviewed all of Ms. Brown's Inteum database entries for accuracy from approximately October 2007 until approximately February 2009. Once Ms. Brown made a database entry based on receipt of a patent document, Ms. Sherwood reviewed the original PTO or other patent office document to confirm that the appropriate dates had been entered into the database to generate the appropriate patent prosecution or maintenance deadlines. Ms. Sherwood only reviewed the accuracy of the entered information, and did not independently track whether every patent document that was received by CDC TTO was docketed. Ms. Brown performed her duties well while her work was being reviewed by Ms. Sherwood, and Ms. Brown gained the confidence of Ms. Sherwood and others at CDC TTO in the performance of these Inteum database duties. There was no indication during this extended time period that Ms. Brown had overlooked entering any Office Action or other patent related deadline. Ms. Brown continued to perform her duties well, and by February 2009 she was evaluated by Andrew Watkins, the then-Director of the CDC TTO, and found to be capable of continuing to perform her Inteum database duties without further training. From that date until the present time she has continued to update the Inteum database at CDC without review of her database entries.

Conclusion

As noted in the Opinion, a delay resulting from an error, such as a docketing error on the part of an employee in the performance of a clerical function may provide the basis for a showing of the "unavoidable" delay. There was a delay of approximately 2.66 years from the expiration of the '944 patent on October 3, 2008 to the filing of the Petition under Rule 37 CFR 1.378(b) on June 1, 2011. The due date for the payment of the 7.5 year maintenance fee for the '944 patent was appropriately generated in the Inteum database when the issuance date of the '944 patent was entered into the database in the year 2000. The need to pay the maintenance fee was noted by Mr. Fikovsky in a May 15, 2008 email to Ms. Shope. In view of Mr. Fikovsky's quarter century of experience as a patent professional, and his particular expertise having set up a system for the payment of maintenance fees at the University of California, it was due care for the Government to have reasonably relied on him for the tracking and payment of the 7.5 year maintenance fee that was appropriately docketed in the CDC's Inteum database. However, contrary to these reasonable expectations of the Government, Mr. Fikovsky did not perform that task through inadvertence.

Similarly, it was reasonable for the Government to have relied on its CDC TTO Inteum IP database manager Veronica Brown, to carry out her docketing duties. Ms. Brown's clerical error in not docketing the November 3, 2008 Notice of Expiration was an exception to her previous record. She had worked at CDC TTO for approximately eight years at the time of the docketing error, and had been trained by Ms. Sherwood who reviewed all docketing entries for more than a year by the time the November 3, 2008 Notice of Expiration arrived at CDC TTO. The Inteum IP database was a reliable patent management program that was and is still used by many technology transfer offices, and the data was being entered into the CDC patent database by a trusted employee who had worked in the office for approximately eight years, and who had been extensively trained by the prior database manager, Ms. Sherwood.

The indicated errors of Mr. Fikovsky and Ms. Brown were the cause of the approximately 2.66 year delay in paying the maintenance fee after the October 3, 2008 expiration date of the '944 patent. The Government knew the maintenance fees were to be paid, and had a business routine in place for performing the function of tracking the maintenance fee payment. This business routine included the purchase and updating of the Inteum IP database, and hiring a Management and Program Analyst (Ms. Brown) whose job it was to maintain the database. Ms.

WDN nms 03/27/12 2091647 doc E-021-91

Brown was trained extensively for over a year at the time of her error in not entering the Notice of Expiration into the Inteum database. Although the Notice of Expiration was received on November 28, 2008 the clerical error that resulted in it not being docketed further delayed the late payment of the maintenance fee by inaccurately omitting the information that the patent had expired. The Government reasonably placed reliance on Mr. Fikovsky and Ms. Brown to carry out their duties, and the mistakes that were made in the furtherance of those duties represent an unavoidable delay on the part of the Government to pay the 7.5 year maintenance fee.

The Opinion requested additional information about the training and experience of Ms. Shropshire, however the Government respectfully submits that information is not pertinent because Ms. Brown received the Notice of Expiration on December 9, 2008 even though Ms. Shropshire did not place it in Ms. Brown's inbox when the Notice of Expiration was received on November 28, 2008. The Opinion also requested information about the close-out procedures with the Government's prior counsel, Needle & Rosenberg, with respect to the shipment of active files directly to the CDC. However, since the Opinion indicates that CDC's reliance on outside counsel to track and pay the fees is without merit, the Government respectfully submits that information about the close-out procedures would similarly be irrelevant. Instead, the Government has demonstrated that it had its own business routines in place to track the maintenance fee payment dates with the Inteum database, that the Government had trained and experienced personnel to carry out those business routines, and that it was the exercise of due care to rely on those Government personnel. However, if the Government has misunderstood the relevance of the information about the close-out procedures and the training and experience of Ms. Shropshire in view of the Opinion, Petitioner requests that the Petitions Attorney provide an opportunity to submit that information.

It is therefore respectfully submitted that the Petition to accept late payment of the maintenance fee under 37 CFR 1.378(b) should be granted.

One World Trade Center, Suite 1600 121 S.W. Salmon Street Portland, Oregon 97204

Telephone: (503) 595-5300 Facsimile: (503) 595-5301 Respectfully submitted, KLARQUIST SPARKMAN, LLP

William D. Noonan, M.D. Registration No. 30,878